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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/666,185 | 09/17/2003 | Reynolds Gorsuch | TRANSVI.007DV1 | 8793 |

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| EXAMINER |
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KIM, SUN U

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| ART UNIT | PAPER NUMBER |
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1723

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|---|--|--|
| <p align="center">Office Action Summary</p> | <p>Application No.</p> <p>10/666,185</p> | <p>Applicant(s)</p> <p>GORSUCH ET AL.</p> | |
| | <p>Examiner</p> <p>John Kim</p> | <p>Art Unit</p> <p>1723</p> | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/17/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15-22, 24-30 and 32 is/are rejected.
- 7) ☒ Claim(s) 12, 14, 23 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>091703</u> | 6) <input type="checkbox"/> Other: _____ |

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1. Information disclosure statement filed 9/17/03 has been considered by the examiner.
2. Claims 23, 26 and 29 are objected to because of the following informalities: A scientific unit is missing for "0.5" on line 2 of claim 23 and "0.75" on line 2 of claims 26 and 29.

Appropriate correction is required.

3. Claim 23 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 23 has not been further treated on the merits.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of "the outer wall surface" in claim 15 lacks a positive antecedent basis.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-11, 13, 15-22, 24-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,034 (Pizziconi et al) in view of European Patent Application 0882494 A1 (EP '494). Pizziconi et al teach an in-vivo ultrafiltration membrane comprising a plurality of asymmetric and anisotropic polysulfone hollow fibers (1) having an integral structure with a fine-pored relatively dense skin over a more porous support layer of the

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same material wherein a pore size of the dense skin layer is in the range of about 0.0025 micron (25 angstroms) to 0.5 micron (5000 angstroms) and lumen of the fibers (1) are connected to a conduit (3) to provide analytes from body fluids for analysis (see figures 1-5; abstract; col. 13, line 62 – col. 14, line 54; col. 15, lines 13-35; col. 16, line 52 – col. 17, line 17; col. 19, line 49 – col. 20, line 39; col. 23, line 5 – col. 24, line 9). Claims 1-11, 13, 15-22, 24-30 and 32 essentially differ from the apparatus of Pizziconi et al in reciting asymmetrical hollow fiber membrane having a continuous change in mass density from the outer wall to the inner wall and comprising a continuum of voids bounded by solid frames. EP '494 teaches an asymmetric hollow fiber membrane having a lower mass density at the inner wall surface and a higher mass density at the outer wall surface (see figure 1); furthermore, the asymmetric hollow fiber membrane is anisotropic which has a network structure which integrally continues from the inner surface to the outer surface and the average pore diameters in the outer surface becomes gradually greater toward the inner surface of the membrane and the inner surface of the membrane has average pore diameter of 5 micron to 30 microns and outer surface of the membrane has average pore diameter of 0.05 micron or more and less than 1 micron which is suitable for ultrafiltration and polysulfone fiber is produced using solvents including polyvinyl pyrrolidone, N-methyl pyrrolidone, dimethyl acetamide, etc. (see figure 1; page 2, lines 5-10; page 2, line 55 - page 3, line 56; page 4, lines 5-32). Such gradual increasing pore size from the outer surface to inner surface shows a continuous change in mass density from the outer wall to the inner wall and comprises a continuum of voids bounded by solid frames as shown in figure 1 and furthermore, such structure includes a number of concentric circumferential zones with different mass densities. It would have been obvious to a person of ordinary skill in the art at the

time the invention was made to substitute the asymmetrical hollow fiber membrane of EP '494 for the asymmetrical hollow fiber membrane of Pizziconi et al for ultrafiltering body fluids to provide analytes for analysis.

8. Applicant is advised that should claim 7 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9. Claims 12, 14 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,834,583 teaches block copolymers to modify the surface of hydrophobic membrane. U.S. Patent No. 5,762,798 and 5,846,422 and 6,258,272 teaches asymmetric membranes.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

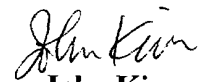
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for official response is (703) 872-9306.

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When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



John Kim
Primary Examiner
Art Unit 1723

J. Kim
December 19, 2003